PATENT
Attorney Docket **036870-5062-01**

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Application of: **Michael Zasloff *et al.***	)	Confirmation No. **5537**
Application No. **09/885,247**	)	Group Art Unit: **1617**
Filed: **July 13, 2000**	)	Examiner: **Yong Soo Chong**
For: **Therapeutic Uses for Aminosterol Compounds**	)	Date: November 27, 2006

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TRANSMITTAL FORM

1. Transmitted herewith is Appellants' Brief Under 37 C.F.R. 41.37.

2. Extension of Time: The proceedings herein are for a patent application and the provisions of 37 C.F.R. 1.136(a) apply. Appellants' Brief Under 37 C.F.R. 41.37 is being timely filed under the next business day rule on Monday, November 27, 2006 as the due date for responding fell on a weekend (Sunday, November 26, 2006). Applicants do not believe an extension of time is required. However, if Applicants have overlooked the need for an extension of time, please consider this a petition therefore. The Commissioner is hereby authorized to charge any additional fees which may be required, including fees due under 37 C.F.R. 1.16 and 1.17, or credit any overpayment to Deposit Account 50-0310.

3. Fee Payment: The Commissioner is hereby authorized to charge **$250.00** to Deposit Account No. 50-0310 for payment of the fee for the filing of a brief in support of an appeal, said fee being submitted at the small entity rate.

4. Constructive Petition: **Except** for issue fees payable under 37 C.F.R. 1.18, the Commissioner is hereby authorized by this paper to charge any additional fees during the entire pendency of this application including fees due under 37 C.F.R. 1.16 and 1.17 which may be required, including any required extension of time fees, or credit any overpayment to Deposit Account 50-0310. This paragraph is intended to be a **constructive petition for extension of time** in accordance with 37 C.F.R. 1.136(a)(3).

Respectfully submitted,
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Dated: **November 27, 2006**
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Application of: **Michael Zasloff *et al.***	Confirmation No. **5537**
Application No. **09/885,247**	Group Art Unit: **1617**
Filed: **July 13, 2000**	Examiner: **Yong Soo Chong**
Title: **Therapeutic Uses for Aminosterol Compounds**	

Date: November 27, 2006

APPELLANTS' BRIEF UNDER 37 C.F.R. § 41.37

This brief is in furtherance of the Notice of Appeal filed in the above-identified patent application on September 26, 2006. A fee of $250.00 as required under 37 C.F.R. §41.20(b)(2) is being filed concurrently herewith. The period for filing this brief extends through November 26, 2006. Because November 26 fell on a Sunday, this response is being timely filed on Monday, November 27.

1. The Real Party in Interest

The real party in interest in this appeal is Genaera Corporation of Plymouth Meeting, Pennsylvania.

2. Related Appeals and Interferences

Appellants are not aware of any other appeals or interferences that will directly affect, or be directly affected by, or have a bearing on the Board's decision in this appeal.

3. Status of Claims

The status of the claims is as follows upon filing of this Appeal Brief:

Claims cancelled: 1 to 13

Claims withdrawn from consideration but not cancelled: None

Claims pending: 14 to 30

Claims objected to: None

Claims allowed: None

Claims rejected: 14 to 30

The claims on appeal are 14 to 30.

4. The Status of Amendments

Appellants filed an Amendment and Response with a Request for Continued Examination on January 9, 2006 in which claims 15, 16, 18 and 19 were amended. The Examiner subsequently issued a Final Office Action in which the amendments to claims 15, 16, 18 and 19 were entered but the rejection of all claims was maintained. As such, Appellants submit that claims 14-30 are the currently pending claims of record. The claims listed in the claims appendix herein incorporate the claim amendments of the aforementioned Amendment and Response.

5. Summary of Claimed Subject Matter

An aspect of Appellants' present invention relates generally to a method for reducing blood cholesterol levels in a mammal suffering from hypercholesteremia. In accordance with the exemplary embodiment of the invention of independent claim 14, this method comprises administering to the mammal an effective amount of a composition comprising a compound of the structural formula shown at page 5, lines 8-9 of the specification. This aspect of Appellants' invention is described in the specification at, *inter alia*, Example 4 (page 14, line 20 to page 15, line 22).

Another aspect of Appellants' present invention relates generally to a method for reducing blood glucose levels in a mammal suffering from diabetes. In accordance with the exemplary embodiment of the invention of independent claim 17, this method comprises administering to the mammal an effective amount of a composition comprising a compound of the structural formula shown at page 5, lines 8-9 of the specification. This aspect of Appellants' invention is described in the specification at, *inter alia*, Example 2 (page 12, line 15 to page 13, line 18).

6. Grounds of Rejection to be Reviewed on Appeal

Whether claims 14 to 30 are unpatentable under 35 U.S.C. § 103(a) as obvious over U.S. Patent No. 5,792,635 ("the '635 patent") or U.S. Patent No. 5,840,740 ("the '740 patent") in view of the Merck Manual of Diagnosis and Therapy, 17th Edition ("the Merck Manual").

In the Final Office Action dated June 26, 2006, claims 14 to 30 were rejected as obvious over the '635 patent or the '740 patent in view of the Merck Manual. In support of his rejection, the Examiner asserts that the '635 and the '740 patents teach the administration of compound 1436 (and additionally compound 412 in the '740 patent) with a pharmaceutically acceptable carrier for treating "cardiac infarction, angina pectoris and ischemic disorders of the heart, and anti-ateriosclerotic (*sic*) and diabetic composition and diabetes, and hypertension in a mammal" (page 4 of the Office Action, lines 2-13). Although the Examiner acknowledges that the '635 and the '740 patents do not expressly teach the use of a compound in a method for reducing blood cholesterol levels in a mammal suffering from hypercholesteremia, he relies on the Merck Manual for teaching that disease states such as cardiac infarction and angina pectoris are

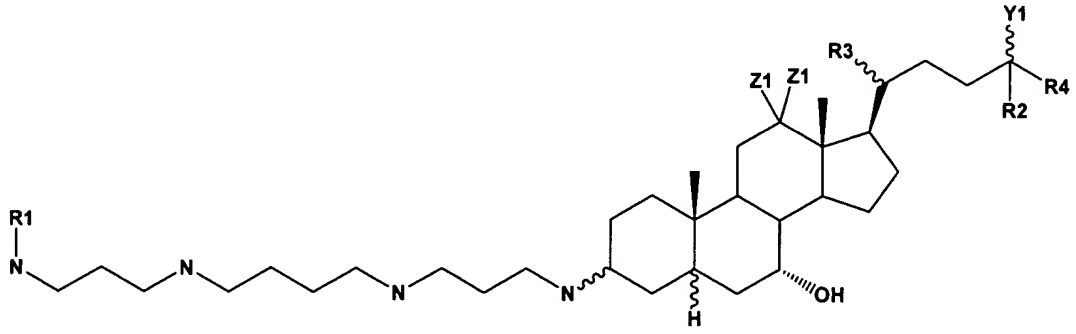
representative of atherosclerosis, which also encompasses hypercholesteremia. Therefore, the Examiner asserts that the '635 and the '740 patents effectively teach treatment of hypercholesteremia and that it would have been obvious for a person of ordinary skill in the art at the time of the invention to employ the compounds of the '635 and the '740 patents in methods of treating hypercholesteremia (see page 5, line 8 to page 6, line 11 of the Office Action).

7. Argument

Appellants respectfully submit that the rejection of claims 14 to 30 under 35 U.S.C. § 103(a) is improper and should be reversed.

A. Independent Claims 14 and 17

With respect to independent claim 14, Appellants respectfully submit that the applied references do not teach or suggest a method for reducing blood cholesterol levels in a mammal suffering from hypercholesteremia, comprising administering to the mammal an effective amount of a composition comprising a compound of the following formula:



wherein

R1 = H or C_1-C_6 alkyl;

R2 = H or C_1-C_3 alkyl-X where X = H, OH, Cl, Br, I or F;

R3 = H or C_1-C_3 alkyl;

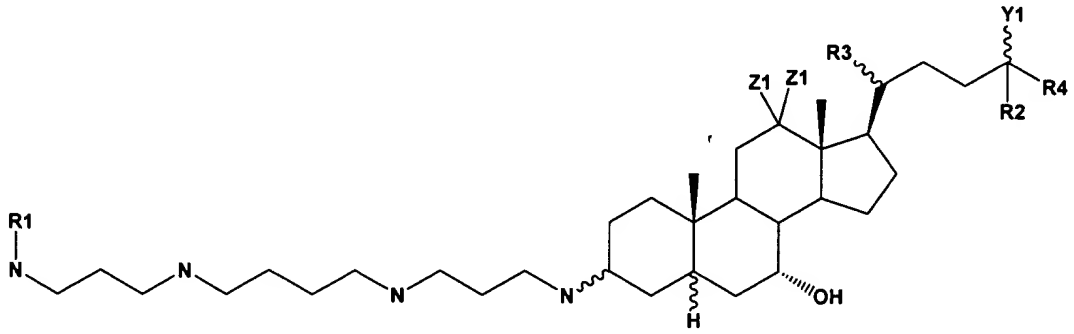
R4 = H or C_1-C_3 alkyl;

Y1 = CO_2H, $NHSO_2CF_3$, SO_3H, PO_3H_2, OSO_3H, CF_3 or F; and

Z1 = H or OH

or a pharmaceutically acceptable salt thereof.

With respect to independent claim 17, Appellants respectfully submit that the applied references do not teach or suggest a method for reducing blood glucose levels in a mammal suffering from diabetes, comprising administering to the mammal an effective amount of a composition comprising a compound of the following formula:



wherein

R1 = H or C_1-C_6 alkyl;

R2 = H or C_1-C_3 alkyl-X where X = H, OH, Cl, Br, I or F;

R3 = H or C_1-C_3 alkyl;

R4 = H or C_1-C_3 alkyl;

Y1 = CO_2H, $NHSO_2CF_3$, SO_3H, PO_3H_2, OSO_3H, CF_3 or F; and

Z1 = H or OH

or a pharmaceutically acceptable salt thereof.

1. Rejection of Claim 14 under 35 U.S.C. 103(a) over the '635 patent or the '740 patent in view of the Merck Manual

The '635 and the '740 patents disclose the following:

> "the development of various NHE-specific inhibitors would allow for the development of new therapies for a whole host of diseases or conditions, including: treating arrhythmias; treating and preventing cardiac infarction; treating and preventing angina pectoris and ischemic disorders of the heart; treating and

> preventing ischemic disorders of the peripheral and central nervous system; treating and preventing ischemic disorders of peripheral organs and limbs; treating shock; providing anti-arteriosclerotic agents; treating diabetic complications; treating cancers; treating fibrotic diseases, including fibroses of lung, liver and kidney; and treating prostatic hyperplasia. Other therapeutic targets include: treatment of viral disease, such as HIV, HPV and HSV; prevention of malignancies; prevention of diabetes (i.e., islet cell injury); prevention of vascular complications of diabetes; treatment of disorders of abnormal neovascularization, e.g., macular degeneration, rheumatoid arthritis, psoriasis, cancer, malignant hemangiomas; prevention of vascular retenosis; prevention of hypertension-associated vascular damage; immunosuppression; and treatment of collagen vascular disorders" (col. 4, lines 2-21 of the '635 and the '740 patents).

Hypercholesteremia is not disclosed by the '635 or the '740 patents. The Examiner acknowledges this fact and further admits that neither the '635 nor the '740 patent discloses a method of using a compound for reducing blood cholesterol levels in a mammal or reducing blood cholesterol levels in a mammal suffering from hypercholesteremia. However, Appellants' claim 14 is still considered to be obvious in view of the '635 and the '740 patents because the Examiner asserts that the listed disease states of "cardiac infarction," "angina pectoris" and "ischemic disorders of the heart" are encompassed by the generic term "atherosclerosis" as defined by pages 1654-1656 of the Merck manual. The Examiner therefore asserts that the '635 and the '740 patents teach the treatment of atherosclerosis and points to page 1656 of the Merck manual as disclosing elevated serum cholesterol as a major risk factor of atherosclerosis. It is the Examiner's conclusion that because the '635 and the '740 patents teach the treatment of specific disease states that may be various manifestations of atherosclerosis, and because elevated serum cholesterol is a major risk factor for atherosclerosis, then a person of ordinary skill in the art

would have reasonably expected aminosterols to be effective in reducing serum cholesterol levels, particularly in patients suffering from hypercholesteremia.

Appellants submit that the Examiner has not set forth a *prima facie* case of obviousness regarding claim 14 because at the very least, a person of ordinary skill in the art would not have a reasonable expectation of success of using the aminosterols set forth in claim 14 to reduce blood cholesterol levels in a mammal suffering from hypercholesteremia. For one, the successful treatment of a specific risk factor such as hypercholesteremia by selected aminosterols cannot reasonably be expected simply because some aminosterols may be successful in treating a disease state that may have resulted, in part, from that risk factor. Second, the only experiments described in the '635 and the '740 patents that even remotely relate to aminosterol-induced arterial effects show (1) the inhibition in the proliferation of arterial smooth muscle and (2) the reduction in arterial blood pressure (see col. 80, lines 9-32 and col. 81, lines 10-42 of the '740 patent and col. 83, line 65 to col. 84, line 23 and col. 85, lines 3-38 of the '635 patent). Neither of these observed anti-proliferative or vasodilative effects of aminosterols would motivate a person of ordinary skill in the art to use these aminosterols in reducing serum cholesterol levels with any reasonable expectation of success. For at least the above-discussed reasons, Appellants request that this rejection be withdrawn.

2. Rejection of Claim 17 under 35 U.S.C. 103(a) over the '635 patent or the '740 patent in view of the Merck Manual

Although the Examiner appears to rely on the combination of the '635 patent or the '740 patent with the Merck Manual in rejecting claim 17, the Examiner's comments in the Office Action dated June 26, 2006 are directed to the reduction of blood cholesterol levels that is the focus of claim 14 and not to the reduction of blood glucose levels that is the focus of claim 17. Thus, it is unclear from the office action as to the reasons for rejection of claim 17 and all claims dependent thereon. The only specific reference to claim 17 occurs in the "Response to Arguments" section where the Examiner indicates that the claim language "reducing blood glucose levels" is considered preamble and will therefore be "given little patentable weight."

In a telephone conference on August 2, 2006, the Examiner, when questioned regarding his belief in the pertinence of the '635 or the '740 patents in teaching the use of select

aminosterols for the treatment of diabetes, pointed to one sentence in the specification indicating that "the development of various NHE-specific inhibitors would allow for the development of new therapies for a whole host of diseases or conditions, including...treating diabetic complications..." (col. 4, lines 1-10).

Appellants submit that the Examiner has not set forth a *prima facie* case of obviousness regarding claim 17 because at the very least, a person of ordinary skill in the art would not have a reasonable expectation of success of using aminosterols to reduce blood glucose levels in a mammal suffering from hypercholesteremia. In fact, the '635 and the '740 patents clearly teach away from the use of select aminosterols for the reduction of blood glucose levels as is shown by the data in Table 11 and the accompanying discussion (see col. 79, line 28 to col. 80, line 8 of the '740 patent; col. 83, lines 17-64 of the '635 patent). For example, Table 11 in the '635 and the '740 patents shows that three selected aminosterols of the described invention actually significantly **increase** blood glucose levels ("between 2-3 fold") in fasting, but otherwise normal, mice (*i.e.*, mice not suffering from diabetes). Since the hyperglycemia observed in these mice treated with the aminosterols was assumed to result from inhibition of insulin secretion, it was suggested that the long-term chronic administration of the aminosterols "may be of value in preventing or delaying the onset of both Type I and Type II diabetes" (col. 80, lines 2-8 of the '740 patent; col. 83, lines 61-64 of the '635 patent). There is no other disclosure present in the specifications of the '635 or the '740 patents that is inconsistent with this teaching of the use of aminosterols for the prevention of diabetes in otherwise healthy mammalian subjects based on the observed increase in blood glucose levels after administration of the aminosterols. There is no indication in the specification of the '635 or the '740 patents of the use of the described aminosterols for the treatment of diabetes. The section of the specification of the '635 and the '740 patents cited by the Examiner as allegedly rendering Appellants' claim 17 obvious includes a statement that aminosterols may be useful for the treatment of diabetic complications. Just 5 lines later the specification states that aminosterols may also be useful for the prevention of diabetes (see col. 4, line 15 of the '635 and the '740 patents). Accordingly, it is readily apparent that the inventors of the '635 and the '740 patents considered the treatment of diabetic complications as separate and distinct from the treatment of diabetes – otherwise they would have simply said "the treatment of diabetes and its complications" or "the treatment and

prevention of diabetes." Accordingly, the Examiner has no basis in concluding that either of the '635 and the '740 patents teach the treatment of diabetes.

In contrast the observations of the '635 and the '740 patents, Appellants' claimed invention is directed to a method of **reducing** blood glucose in a mammal actually suffering from diabetes comprising administration of the recited aminosterols. In surprising and unexpected results, Appellants found that the same aminosterol compounds that increased blood glucose levels in mammals predisposed to diabetes as observed and reported in the '635 and the '740 patents, actually did the opposite (*i.e.*, decreased blood glucose levels) in mammals suffering from diabetes.

Appellants emphasize that the mammalian model used in the '635 and the '740 patents to test blood glucose levels in subjects dosed with selected aminosterols is very different from the mammalian used by Appellants in the subject application. The mammals tested as described in the '635 and the '740 patents were healthy while the mammals tested as described in the subject application were suffering with diabetes. Clearly, a person of ordinary skill in the art who observed the significant elevation of blood glucose in healthy mammals dosed with various aminosterols would not have expected that the same aminosterols (*e.g.*, compound 1436) would have significantly decreased blood glucose levels in mammals suffering from diabetes. The Merck Manual does not remedy these discussed deficiencies present in the '635 or the '740 patent disclosures. For at least this reason, Appellants request that this rejection be withdrawn.

For at least the above stated reasons in sections 1 and 2, Appellants respectfully submit that the subject matter recited by independent claims 14 and 17 is both novel and nonobvious over the teachings of the '635 or the '740 patents alone or in combination with the Merck Manual. Accordingly, Appellants respectfully submit that the rejections of independent claims 14 and 17 are improper and should be reversed.

B. Dependent Claims 15, 16 and 18-30

Appellants respectfully assert that dependent claims 15, 16 and 18-30 are individually allowable at least because of their respective dependencies from independent claims 14 and 17 and for the reasons set forth above. Thus, the rejection of dependent claims 15, 16 and 18-30 are improper and should be reversed.

The '635 and the '740 patents, either alone or in view of the Merck Manual, do not teach or suggest claim 15, which depends from claim 14 and further limits the method to wherein the cholesterol levels are reduced in the sera of the blood.

The '635 and the '740 patents, either alone or in view of the Merck Manual, do not teach or suggest claim 16, which depends from claim 14 and further limits the method to wherein the cholesterol levels are reduced in the plasma of the blood.

The '635 and the '740 patents, either alone or in view of the Merck Manual, do not teach or suggest claim 18, which depends from claim 17 and further limits the method to wherein the glucose levels are reduced in the sera of the blood.

The '635 and the '740 patents, either alone or in view of the Merck Manual, do not teach or suggest claim 19, which depends from claim 17 and further limits the method to wherein the glucose levels are reduced in the plasma of the blood.

The '635 and the '740 patents, either alone or in view of the Merck Manual, do not teach or suggest claim 20, which depends in the alternative from claim 14 or claim 17 and further limits the method to wherein the composition is administered in an amount of from about 0.01 mg/kg of body weight/day to about 100 mg/kg of body weight/day. More specifically, the '635 and the '740 patents do not describe suitable dosing levels of aminosterols for the reduction of blood cholesterol levels or blood glucose levels because the use of aminosterols for these purposes are not contemplated.

The '635 and the '740 patents, either alone or in view of the Merck Manual, do not teach or suggest claim 21, which depends from claim 20 and further limits the method to wherein the composition is administered in an amount of from about 0.1 mg/kg of body weight/day to about 25 mg/kg of body weight/day. More specifically, the '635 and the '740 patents do not describe suitable dosing levels of aminosterols for the reduction of blood cholesterol levels or blood glucose levels because the use of aminosterols for these purposes are not contemplated.

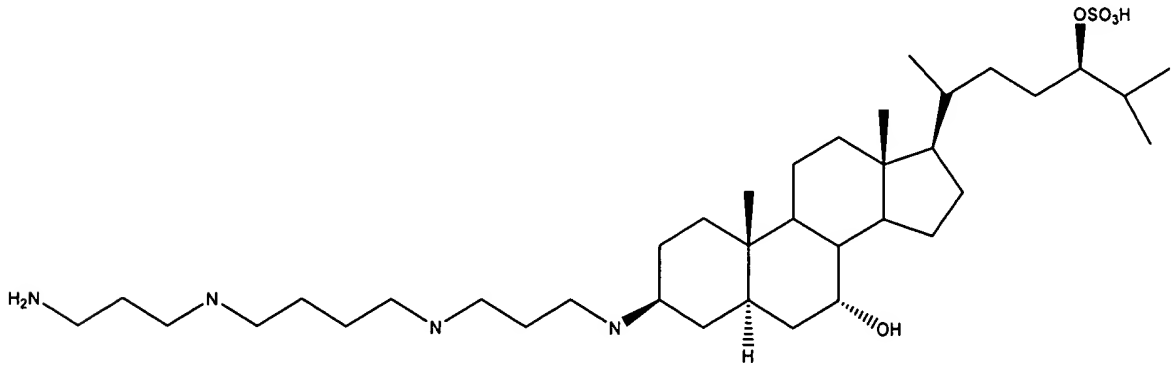
The '635 and the '740 patents, either alone or in view of the Merck Manual, do not teach or suggest claim 22, which depends in the alternative from claim 14 or claim 17 and further limits the method to wherein the composition is administered transdermally, intramuscularly, intravenously, subcutaneously, intranasally, topically or orally.

The '635 and the '740 patents, either alone or in view of the Merck Manual, do not teach or suggest claim 23, which depends from claim 22 and further limits the method to wherein the composition is administered subcutaneously or intravenously.

The '635 and the '740 patents, either alone or in view of the Merck Manual, do not teach or suggest claim 24, which depends in the alternative from claim 14 or claim 17 and further limits the method to comprising a pharmaceutically acceptable carrier or excipient.

The '635 and the '740 patents, either alone or in view of the Merck Manual, do not teach or suggest claim 25, which depends in the alternative from claim 14 or claim 17 and further limits the method to wherein the mammal is a human.

The '635 and the '740 patents, either alone or in view of the Merck Manual, do not teach or suggest claim 26, which depends from claim 14 and further limits the method to wherein the compound is

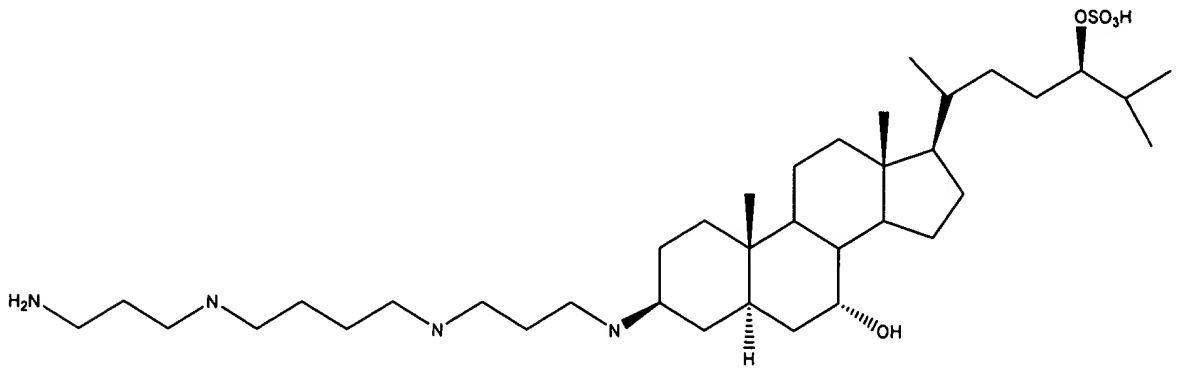


or a pharmaceutically acceptable salt thereof. More specifically, neither the '635 nor the '740 patent contemplates the use of compound 1436 for the reduction of blood cholesterol levels in afflicted mammals.

The '635 and the '740 patents, either alone or in view of the Merck Manual, do not teach or suggest claim 27, which depends from claim 26 and further limits the method to wherein the hypercholesteremia is associated with obesity.

The '635 and the '740 patents, either alone or in view of the Merck Manual, do not teach or suggest claim 28, which depends from claim 26 and further limits the method to comprising a pharmaceutically acceptable carrier or excipient.

The '635 and the '740 patents, either alone or in view of the Merck Manual, do not teach or suggest claim 29, which depends from claim 17 and further limits the method to wherein the compound is



or a pharmaceutically acceptable salt thereof. More specifically, neither the '635 nor the '740 patent contemplates the use of compound 1436 for the reduction of blood glucose levels in afflicted mammals.

The '635 and the '740 patents, either alone or in view of the Merck Manual, do not teach or suggest claim 30, which depends from claim 29 and further limits the method to comprising a pharmaceutically acceptable carrier or excipient.

In view of the foregoing, Appellants respectfully request the reversal of the Examiner's rejections and the allowance of the pending claims. If there are any other fees due in connection with the filing of this Appellants' Brief, please charge the fees to our Deposit Account No. 50-0310.

If a fee is required for an extension of time under 37 C.F.R. §1.136 not accounted for above, such an extension is requested and the fee should also be charged to our Deposit Account No. 50-0310.

Respectfully submitted,

MORGAN LEWIS & BOCKIUS LLP

Dated: **November 27, 2006** By: _____

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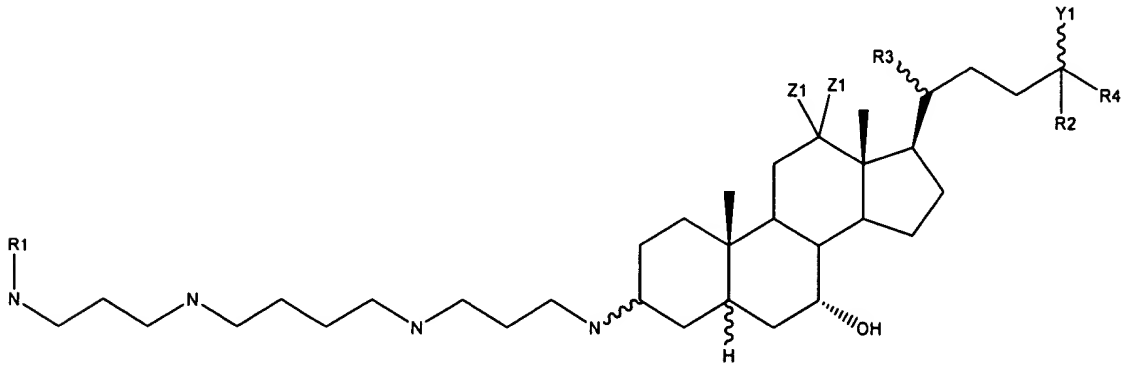
8. Claims Appendix

Subsequent to entry of the Amendment and Response under 37 C.F.R. § 1.114, the claims read as follows:

Claims 1-13 (cancelled).

Claim 14. A method for reducing blood cholesterol levels in a mammal suffering from hypercholesteremia, comprising

administering to the mammal an effective amount of a composition comprising a compound of the following formula:



wherein

R1 = H or C_1-C_6 alkyl;

R2 = H or C_1-C_3 alkyl-X where X = H, OH, Cl, Br, I or F;

R3 = H or C_1-C_3 alkyl;

R4 = H or C_1-C_3 alkyl;

Y1 = CO_2H, $NHSO_2CF_3$, SO_3H, PO_3H_2, OSO_3H, CF_3 or F; and

Z1 = H or OH

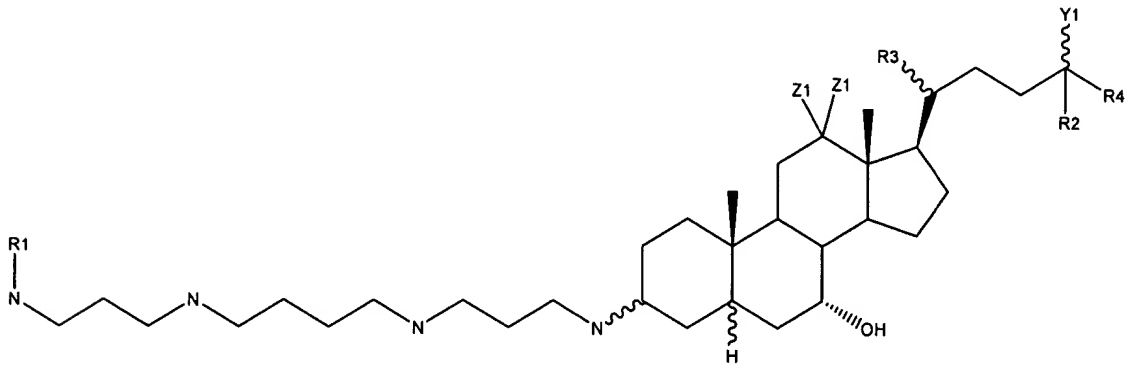
or a pharmaceutically acceptable salt thereof.

Claim 15. The method according to claim 14, wherein the cholesterol levels are reduced in the sera of the blood.

Claim 16. The method according to claim 14, wherein the cholesterol levels are reduced in the plasma of the blood.

Claim 17. A method for reducing blood glucose levels in a mammal suffering from diabetes, comprising

administering to the mammal an effective amount of a composition comprising a compound of the following formula:



wherein

R1 = H or C_1-C_6 alkyl;

R2 = H or C_1-C_3 alkyl-X where X = H, OH, Cl, Br, I or F;

R3 = H or C_1-C_3 alkyl;

R4 = H or C_1-C_3 alkyl;

Y1 = CO_2H, $NHSO_2CF_3$, SO_3H, PO_3H_2, OSO_3H, CF_3 or F; and

Z1 = H or OH

or a pharmaceutically acceptable salt thereof.

Claim 18. The method according to claim 17, wherein the glucose levels are reduced in the sera of the blood.

Claim 19. The method according to claim 17, wherein the glucose levels are reduced in the plasma of the blood.

Claim 20. The method according to claim 14 or claim 17, wherein the composition is administered in an amount of from about 0.01 mg/kg of body weight/day to about 100 mg/kg of body weight/day.

Claim 21. The method according to claim 20, wherein the composition is administered in an amount of from about 0.1 mg/kg of body weight/day to about 25 mg/kg of body weight/day.

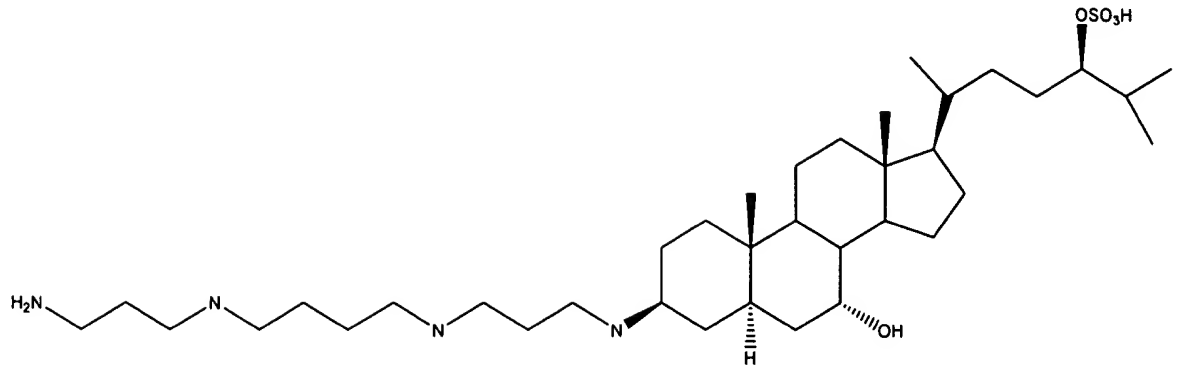
Claim 22. The method according to claim 14 or claim 17, wherein the composition is administered transdermally, intramuscularly, intravenously, subcutaneously, intranasally, topically or orally.

Claim 23. The method according to claim 22, wherein the composition is administered subcutaneously or intravenously.

Claim 24. The method according to claim 14 or claim 17, further comprising a pharmaceutically acceptable carrier or excipient.

Claim 25. The method according to claim 14 or claim 17, wherein the mammal is a human.

Claim 26. The method according to claim 14, wherein the compound is

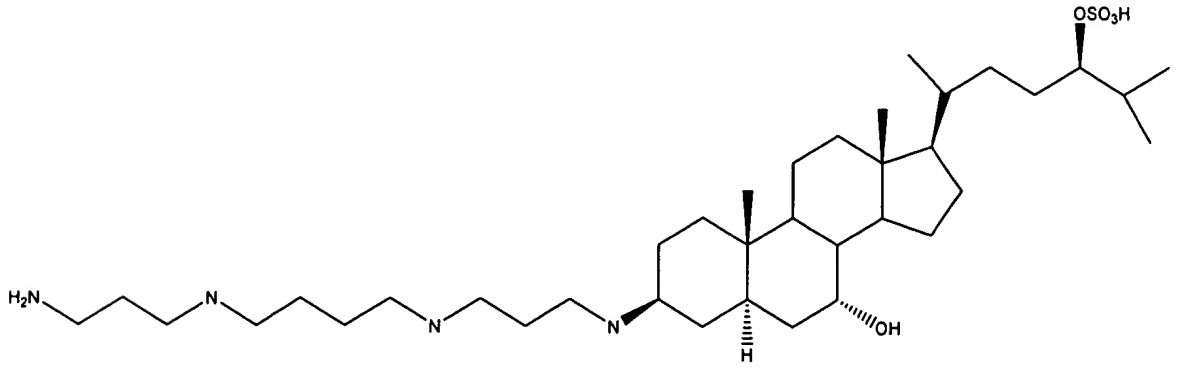


or a pharmaceutically acceptable salt thereof.

Claim 27. The method according to claim 26, wherein the hypercholesteremia is associated with obesity.

Claim 28. The method according to claim 26, further comprising a pharmaceutically acceptable carrier or excipient.

Claim 29. The method according to claim 17, wherein the compound is



or a pharmaceutically acceptable salt thereof.

Claim 30. The method according to claim 29, further comprising a pharmaceutically acceptable carrier or excipient.

9. Evidence Appendix

No information is appended under this section.

10. Related Proceedings Appendix

No information is appended under this section.